

DEC - 7 2004

Summary of Safety and Effectiveness  
Liquichek Specialty Immunoassay Control

1.0 **Submitter**

Bio-Rad Laboratories  
9500 Jeronimo Road,  
Irvine, California 92618-2017  
Telephone: (949) 598-1200  
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**Contact Person**

Suzanne Parsons  
Regulatory Affairs Specialist  
Telephone: (949) 598-1467

**Date of Summary Preparation**

November 2, 2004

2.0 **Device Identification**

Product Trade Name: Liquichek Specialty Immunoassay Control  
Common Name: Multi-analyte controls, (assayed and unassayed)  
  
Classifications: Class I  
  
Product Code: JJY  
  
Regulation Number: 21 CFR 862.1660

3.0 **Device to Which Substantial Equivalence is Claimed**

Lyphocheck Immunoassay Plus Control  
Bio-Rad Laboratories  
Irvine, California

510 (k) Number: K981532

4.0 **Description of Device**

Liquichek Specialty Immunoassay Control is prepared from human serum with added constituents of human and animal origin, chemicals, stabilizers, and preservatives. This product is provided in liquid form.

5.0 **Intended Use**

Liquichek Specialty Immunoassay Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for analyte listed in the package insert.

## 6.0 Comparison of the new device with the Predicate Device

Liquichek Specialty Immunoassay Control claims substantial equivalence to the Lyphochek Immunoassay Plus Control currently in commercial distribution (K981532). Both products are serum based products that contain multiple analytes used to monitor precision of laboratory testing procedures.

**Table 1.** Similarities and Differences between new and predicate device.

Characteristics	Bio-Rad Laboratories Bio-Rad Liquichek Specialty Immunoassay Control (New Device)	Bio-Rad Laboratories Lyphochek Immunoassay Plus Control (Predicate Device K981532)
<b>Similarities</b>		
<b>Intended Use</b>	Liquichek Specialty Immunoassay Control is intended for use as quality control serum to monitor the precision of laboratory testing procedures listed in the package insert.	Lyphochek Immunoassay Plus Control is intended for use as quality control serum to monitor the precision of laboratory testing procedures listed in the package insert
<b>Stabilizers</b>	Contains Stabilizers	Contains Stabilizers
<b>Matrix</b>	Human Serum	Human Serum
<b>Differences</b>		
<b>Form</b>	Liquid	Lyophilized
<b>Preservatives</b>	Contains Preservatives	None
<b>Storage (Unopened)</b>	-20 to -70°C Until expiration date	2 to 8°C Until expiration date
<b>Open Vial</b>	30 days at 2-8°C with the following exceptions: Anti-Tg and Anti-TPO will be stable for 21 days	7 days at 2 to 8 °C with the following exceptions: (1) Folate and PSA will be stable for 3 days after reconstitution, (2) C-Peptide will be stable for 1 day, (3) Intact PTH will be stable for 16 hours after reconstitution, and (4) ACTH, Calcitonin, Gastrin and Free PSA should be assayed immediately after reconstitution.
<b>Alternate storage</b>	None	After reconstituting and freezing: all analytes will be stable for 20 at -10 to -20°C with the following exceptions: no frozen stability claim is supplied for ACTH, Aldosterone, Androstenedione, Calcitonin and C-Peptide.
<b>Analytes</b>	Contains only the following analytes: <ul style="list-style-type: none"> <li>Anti-Tg</li> <li>Anti-TPO</li> <li>C-peptide</li> <li>Erythropoietin (EPO)</li> <li>Intact PTH (iPTH)</li> <li>IGF-I</li> <li>Osteocalcin</li> <li>25-OH Vitamin D</li> </ul>	Contains the following analytes: Multi analyte including: <ul style="list-style-type: none"> <li>25-OH Vitamin D</li> <li>C-peptide</li> <li>Intact PTH (iPTH)</li> </ul> Does not contain: <ul style="list-style-type: none"> <li>Anti-Tg</li> <li>Anti-TPO</li> <li>Erythropoietin (EPO)</li> <li>IGF-I</li> <li>Osteocalcin</li> </ul>

## 7.0 Statement of Supporting Data

Stability studies have been performed to determine the open vial stability and shelf life for the Liquichek Specialty Immunoassay Control. Product claims are as follows:

7.1 Open vial 30 days at 2°C to 8°C with the following exceptions: Anti-Tg and Anti-TPO will be stable for 21 days

7.2 Shelf Life Stability 2 Years at -20 to -70°C

All supporting data is retained on file at Bio-Rad Laboratories.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

DEC - 7 2004

Ms. Suzanne S. Parsons  
Regulatory Affairs Specialist  
Bio-Rad Laboratories, Inc.  
9500 Jeronimo Rd.  
Irvine, CA 92618-2017

Re: k043108

Trade/Device Name: Liquichek Specialty Immunoassay Control  
Regulation Number: 21 CFR 862.1660  
Regulation Name: Quality Control Material (Assayed and Unassayed)  
Regulatory Class: Class I  
Product Code: JJY  
Dated: November 4, 2004  
Received: November 9, 2004

Dear Ms Parsons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

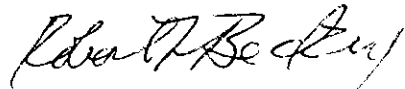
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to legally

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marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Robert L. Becker, Jr.", written in a cursive style.

Robert L. Becker, Jr., M.D., PhD  
Director

Division of Immunology and Hematology Devices  
Office of In Vitro Diagnostic Device Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K043108

Device Name: Liquichek Specialty Immunoassay Control

Indications For Use: Liquichek Specialty Immunoassay Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures listed in the package insert.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

*Maria Chan*  
Division Sign-Off

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Office of In Vitro Diagnostic Device  
Evaluation and Safety

510(k) K043108